REMARKS

This Reply is set forth under appropriate subheadings for the convenience of the Examiner.

Restriction Requirement

In response to a Restriction Requirement, Applicants made an election of Group II and made a further species election with traverse on June 30, 2008. The Examiner maintained the restriction requirement and made it final. Non-elected subject matter has been withdrawn.

In accordance with M.P.E.P. § 821.04(a), Applicants respectfully request that if the method of detecting the presence of, or predisposition to Lafora's disease of Claim 4 is found to be allowable, then withdrawn Claim 49 and new Claim 51, directed to a method of detecting the presence of, or predisposition to Lafora's disease, comprising the detection of specific mutation and to a method of detecting specific mutations in the EPM2B gene, respectively, should be rejoined and examined.

As acknowledged by the Examiner, Claim 4 is a linking claim. Claim 49 depends from and further limits Claim 4 and shares a substantially common structure, namely a mutation in the EPM2B gene, comprising a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1. Similarly, new Claim 51 depends from and further limits Claim 43. Examination of Claims 49 and 51 would not result in a serious search and examination burden, thus, Claim 49 and new Claim 51 should not be withdrawn.

Amendments to Claim 4 and 47 and new Claims 51 and 52

Claims 4 and 47 have been amended and new Claims 51 and 52 have been added to more clearly define that which Applicants regard as the invention. Support for the amendments to Claims 4 and 47 can be found in the specification and claims as originally filed. For example, page 20, lines 28-32 and original Claim 5 describes detecting a C to G change at nucleotide number 205 in the EPM2B gene sequence comprising SEQ ID NO: 1, thereby providing support for the amendment to Claim 4. Page 20, lines 5-8 describe detecting a mutation in the EPM2B gene, thereby providing support for the amendment to Claim 47. Page 20, line 23 through page 21, line 31, Table 1, and original Claims 6-25 describes methods for detecting specific mutations

in the EPM2B gene comprising SEQ ID NO: 1, thereby providing support for new Claim 51. Page 6, line 30 through page 7, line 11 describes determining that a subject is unaffected by Lafora's disease wherein the Lafora's disease is associated with a mutation in the EPM2B gene, thereby providing support to new Claim 52.

No new matter has been added in the amendments to the Claims 4 and 47 or in new Claims 51 and 52. Entry of the amendments to the Claims 4 and 47 or new Claims 51 and 52 is requested.

Rejection of Claim 4 Under 35 U.S.C. § 112, Second Paragraph

Claims 4 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner stated that Claim 4 is indefinite because "It is unclear whether Claim 4 is directed to a method of detecting the presence of or predisposition to Lafora's disease in a human or whether the claim is merely drawn to the detection of a C to G change at nucleotide number 205..."

Claim 4 has been amended to clarify that the claimed method is directed to a method of detecting the presence of, or predisposition to, Lafora's disease.

Thus, Claim 4 satisfies the requirements of 35 U.S.C. § 112, second paragraph, and reconsideration and withdrawal of the rejections is respectfully requested.

Rejection of Claims 4, 43, 47 and 50 Under 35 U.S.C. § 102(a)

Claims 4, 43, 47 and 50 were rejected under 35 U.S.C. § 102(a) as being anticipated by Chan *et al.*, "Mutations in *NHLRC1* cause progressive myoclonus epilepsy" (October 2003), *Nature Genetics*, Vol. 35, pp 125-127. ("Chan *et al.*").

The publication date of Chan *et al.* is after the priority date of the present application. However, the Examiner stated that because "SEQ ID NO: 1 from the provisional application and SEQ ID NO: 1 of the instant application are different .... the instant SEQ ID NO: 1 was not disclosed in the provisional application and the application is awarded priority of the instant filing date."

To claim the benefit of a prior-filed application, the prior-filed application must disclose the claimed invention of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. MPEP 201.11. The present application properly claims the benefit of U.S. Provisional Application No: 60/491,168 filed August 4, 2003. SEQ ID NO:1 as disclosed in the provisional application is 14 nucleotides longer than SEQ ID NO: 1 as disclosed in the present application. These 14 nucleotides are upstream of the putative start codon. The provisional application specifically identifies the putative start and ORF. *See, e.g.*, Figure 6A. The provisional application also discloses that the sequence preceding the start codon "has the proposed features of the consensus sequence ... of an eukaryotic translation initiation site." Page 3, lines 28-31. One of ordinary skill in the art would recognize that SEQ ID NO :1 of the present application is the same as SEQ ID NO:1 of the provisional application, but that SEQ ID NO: 1 of the present application simply lacks the untranslated 14 nucleotides that precede the start codon. Accordingly, the provisional application discloses the claimed invention and the present application should be afforded a priority date of August 4, 2003. Because this date precedes the publication date of Chan *et al.*, that reference is not prior art and the rejection should be withdrawn.

However, solely to speed prosecution, Applicants herewith submit a Declaration Under 37 C.F.R. § 1.132 by Drs. Stephen W. Scherer and Berge A. Minassian ("the declaration"). As noted in *In re Katz*, "[d]isclosure to the public of one's own work constitutes a bar to the grant of a patent claiming the subject matter so disclosed . . . only when the disclosure occurred more than one year prior to the date of the application . . ." (*In re Katz* 215 U.S.P.Q. 14, 17 (CCPA 1982). The present application claims the benefit under 35 U.S.C. §119(e) of U.S. Provisional Application No. 60/491,168, filed August 4, 2003. The Chan *et al.* reference, which is co-authored by Applicants and discloses Applicants' own work, was published within the year before the subject application was filed. Thus, the Chan *et al.* reference is not prior art to Applicant's claimed invention.

This declaration establishes that the remaining co-authors of the Chan *et al.* reference (*i.e.*, Elayne M. Chan, Edwin J. Young, Leonardo Ianzano, Iulia Munteanu, Xiaochu Zhao, Constantine C. Christopoulos, Guiliano Avanzini, Maurizio Elia, Cmeraon A. Ackerley, Nebojsa, J. Jovic, Saeed Bohlega, Eva Andermann, Guy A. Rouleau, and Antonio V Delgado-

Escueta) carried out certain experiments discussed in the reference under the supervision or direction of one or more of the inventors and/or participated in discussions of the results and conclusions presented therein with one or more of the co-inventors of the subject application and did not contribute materially to the conception of the invention claimed in the subject application.

Submission of this declaration obviates that rejection under 35 U.S.C. §102(a).

Rejection of Claim 47 Under 35 U.S.C. § 102(b)

Claim 47 was rejected under 35 U.S.C. § 102(b) as being anticipated by Genbank Number gi13509424, April 30, 2001 (Blakey *et al.*).

The Examiner states that Blakey *et al.* teaches a "DNA sequence from the homo sapiens chromosome 6 clone RP11-204B7 which comprises SEQ ID NO:1. Blakey teaches detecting the presence of EPM2B gene be analyzing a test sample obtained from the human from the presence of a nucleic acid comprising SEQ ID NO: 1."

Blakey *et al.* is a "working draft" of the sequence of a portion of human chromosome 6. and discloses a 170,307bp piece of human chromosome 6 in 3 unordered contigs. Blakey *et al.* does not disclose the EPM2B gene, detecting the presence of the EPM2B gene, or the relationship between the EPM2B gene and Lafora's disease, wherein the EMP2B gene consists of SEQ ID NO: 1.

Because Blakely *et al.* does not disclose the EPM2B gene and does not disclose a method for detecting the presence of the EPM2B gene, wherein the EPM2B gene consists of SEQ ID NO: 1, it does not anticipate the invention as claimed in Claim 47, and reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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